IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	Master File No 2:12-MD-02327 MDL No. 2327
----------	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' MOTION TO COMPEL DISCOVERY AND FOR EXPEDITED HEARING

Plaintiffs, by and through Co-lead Counsel and pursuant to Fed. R. Civ. P. 37(a), file this Motion to Compel Discovery seeking the Court's Order overruling Defendants' objections to Plaintiffs' Rule 30(b)(6) deposition notices and compelling discovery on the subject matters at issue, as set forth below. Further moving, Plaintiffs respectfully request an expedited hearing of this motion as the Rule 30(b)(6) deposition at issue is set for May 15, 2013.

I. BACKGROUND FACTS

A. On April 2 and 3, 2013, Plaintiffs served five Amended Notices to Take Oral Deposition of Defendant Through Designated Witness pursuant to Fed. R. Civ. P. 30(b)(6). (Responses and Objections to Plaintiffs' Notices of 30(b)(6) Deposition of Defendants, which contain Plaintiffs' Rule 30(b)(6) Deposition Notices, attached collectively as Exhibit A.)

B. The Rule 30(b)(6) deposition notices list 34 subject matters about which Defendants' corporate designee(s) shall have knowledge. All 34 subject matters relate to Defendants' design and development of the Tension Free Vaginal Tape ("TVT") products sold by Defendants that are at issue in this litigation, i.e., TVT, TVT-Abbrevo (TVT-A), TVT-Exact (TVT-E), TVT-Obturator (TVT-O), and TVT-Secur (TVT-S). *Id.*

C. In response, Defendants designated a corporate representative to testify regarding the topics – Daniel Smith. Additionally, on April 10, 2013, Defendants served their Responses and Objections to Plaintiffs' Notices of 30(b)(6) Deposition, lodging objections to many of the subject matters upon which Mr. Smith shall testify. *Id.*

E. The deposition of Mr. Smith is currently set for May 15, 2013. *Id.*

F. Notably, on January 15, 2013, Plaintiffs gave notice to Defendants regarding their intent to serve Rule 30(b)(6) deposition notices seeking testimony regarding the subject matters and documents currently at issue. (Correspondence, attached as Exhibit B.) Consequently, Defendants have been on notice of such matters for several months.

G. Plaintiffs, through Co-lead Counsel, have conferred with defense counsel via telephone and written correspondence on numerous occasions regarding the subject matters and objections at issue and, despite a good faith effort to resolve the discovery disputes, have been unable to do so. (Correspondence, attached as Exhibit C.)

H. A statement setting forth each discovery request at issue and Defendants' responses is attached as Exhibit D.

II. STANDARD

"The purpose of discovery is to provide a mechanism for making relevant information available to the litigants." Fed. R. Civ. P. 26 advisory committee's notes, 1983 Amendment. "Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party, including the existence, description, nature, custody, condition, and location of any books, documents, or other tangible things and the identity and location of persons having knowledge of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant

information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). The Fourth Circuit has declared that "[d]iscovery under the Federal Rules of Civil Procedure is *broad in scope and freely permitted." Carefirst of Md., Inc. v. Carefirst Pregnancy Ctrs., Inc.,* 334 F.3d 390, 402 (4th Cir. 2003) (emphasis added). Moreover, the commentary to the Rules indicates that "[a] variety of types of information not directly pertinent to the incident in suit could be relevant to the claims or defenses raised in a given action." Fed. R. Civ. P. 26 advisory committee's notes, 2000 Amendment, Subdivision (b)(1). The party opposing a motion to compel bears the burden of showing why it should not be granted. *Rogers v. Tri–State Materials Corp.,* 51 F.R.D. 234, 247 (N.D.W.V. 1970).

III. ARGUMENT

At the outset, it is worth noting that Defendants' objections to Plaintiffs' Rule 30(b)(6) deposition notices are improper under the Federal Rules of Civil Procedure.

> Unlike the procedure with respect to interrogatories, requests for production of documents and requests for admissions, there is no provision in the rules which provides for a party whose deposition is noticed to serve objections so as to be able to avoid providing the requested discovery until an order compelling discovery is issued. While it is indeed good practice to discuss any issues respecting a 30(b)(6) deposition notice with the party which noticed the deposition in an attempt to work out an agreement, in the absence of an agreement, a party cannot decide on its own to ignore the notice. Rather, if counsel [for Defendant] . . . was of the view that the plaintiff's 30(b)(6) deposition notice was defective or improper in some way or that the information sought was . . . obtainable from some other source . . . such as interrogatories . . . which would be more convenient, less burdensome or less expensive . . . , it was [Defendant's] burden to seek a protection pursuant to Rule 26(c).

New England Carpenters Health Benefits Fund v. First DataBank, Inc., 242 F.R.D. 164, 165 - 166 (D. Mass. 2007).

Regardless of Defendants' procedural error, Plaintiffs seek the Court's Order overruling Defendants' objections to six subject matters listed in their 30(b)(6) deposition notices: (1) the standard operating procedures associated with design and development of the devices; (2) the complete design history file for the devices; (3) the members and procedures of the Product Development Team for the devices; (4) all product names of the devices; (5) any patents relating to the devices; and (6) the manufacturing processes, as they relate to design control and validation. Additionally, Defendants object to one category of documents requested: (1) all company policies and procedures that apply to or relate to the design history file for the devices. Because Defendants' objections are without merit and such topics and documents are wholly appropriate for a 30(b)(6) deposition, the Court should overrule the objections and compel discovery on the subject matters at issue.

A. Topic a: The Standard Operating Procedures (SOP) associated with design and development of the Devices.

Defendants object to this subject matter, arguing that it is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). The purported basis for this argument is that the design and development of the devices were long-term projects, taking more than a dozen years. They claim that it is "impossible for any witness to testify about every version of the [SOP] associated with each device" and there will be numerous SOPs applicable to the design of the devices that have no bearing on this litigation. (Doc. No. 517 at 3.) Moreover, they allege that this topic is improper for a Rule 30(b)(6) deposition as the information can be more efficiently transmitted by a document production. Subject to and without waiving these objections, Defendants agree to produce a witness who will address the

"**most recent SOP**" associated with the design and development of the devices to the best of his or her ability. (*Id.*)

Defendants' argument that this subject matter is overly broad and unduly burdensome due to the length of the projects is meritless. Plaintiffs learned a few months ago (while preparing for the Rule 30(b)(6) deposition of Defendants' regulatory affairs designee, Susan Lin) that Defendants have only been producing "some" of the relevant SOPs. In addition, Plaintiffs learned at that time that with respect to the SOPs that have been produced, they do not have an effective date, only include a partial revision history, and do not include dates associated with the revisions. Rather, Defendants took the position that they would only produce the most recent copies of the SOPs and only allow testimony related to such SOPs. After weeks of meeting and conferring and Plaintiffs waiting, Defendants finally produced some of the relevant SOPs at issue in the regulatory Rule 30(b)(6) deposition, including the effective date, the complete revision history, and the dates of the revisions. We are now, however, less than a week from the start of the Rule 30(b)(6) deposition of Daniel Smith, Defendants' design and development corporate designee, and Defendants have still not agreed to produce all of the relevant design and development SOPs, including the effective dates, the revision history, and the dates of the revisions. This is true even though Plaintiffs have been asking for these SOPs and this information for months.

Clearly, Plaintiffs are entitled to receive ***all*** versions of the relevant SOPs and to question Defendants' corporate designee about ***all*** versions of the relevant SOPs so that Plaintiffs can discover what SOPs were in effect at all relevant times. Bryan Lisa, Ethicon's former Associate Director of Women's Health & Urology, recently testified in this litigation as follows:

> MR. AYLSTOCK: Okay. We have a lot of SOPs. None of them are historical. They are all the current versions as I understand it. I'd like the version that was in place at this point in time.
>
> THE WITNESS: Yeah they are all available electronically in electronic record systems.
>
> BY MR. AYLSTOCK: Q. Is there a database?
>
> A. Yes, sir.
>
> Q. Including the historical ones?
>
> A. Yes, sir they should be maintained.
>
> Q. And the revision dates?
>
> A. It's a controlled system. It's. . . .
>
> Q. Is there a name for that system?
>
> A. When I was there it used to be called ECCS, Ethicon change control system.
>
> Q. It wouldn't be difficult for you when you were there to go back and look at SOPs?
>
> A. That's correct.

(Deposition of Bryan Lisa, attached as Exhibit E, at 216:4-24.) Clearly, Defendants are able to simply and easily access all of the SOPs associated with design and development of their TVT devices.

Even assuming for the sake of argument that locating such SOPs would be somewhat difficult for Defendants, such difficulty is an improper basis for Defendants' instant objection.

> Rule 30(b)(6) implicitly requires the designated representative to review all matters known or reasonably available to the corporation in preparation for the Rule 30(b)(6) deposition. This interpretation is necessary in order to make the deposition a meaningful one and to prevent the sandbagging of an opponent by conducting a half-hearted inquiry before the deposition but a thorough and vigorous one before the trial. This would totally

> defeat the purpose of the discovery process. The Court understands that preparing for a Rule 30(b)(6) deposition can be burdensome. However, this is merely the result of the concomitant obligation from the privilege of being able to use the corporate [or other organizational] form in order to conduct business.

Starlight Int'l Inc. v. Herlihy, 186 F.R.D. 626, 638-39 (D. Kan. 1999) (citing *United States v. Taylor*, 166 F.R.D. 356, 362 (M.D.N.C.), *aff'd*, 166 F.R.D. 367 (1996)).

This litigation involves, *inter alia*, claims that Defendants' TVT products were defectively designed and claims that the TVT products were not substantially similar to a predicate device, as required for FDA 510(k) clearance. Therefore, the SOPs associated with the design and development of ***all*** of Defendants' TVT products clearly is an appropriate and relevant subject for the 30(b)(6) deposition, regardless of the length of the projects. In addition, the revisions to the SOPs and the dates associated with each revision are relevant and appropriate subjects for the deposition as well. Defendants' corporate designee – whom Defendants chose to testify about the subject of design and development – is required to review all matters known or reasonably available to Defendants in preparation for the deposition even if such preparation may be somewhat "burdensome." *Id.* As the Court stated in *Starlight Int'l*, Defendants should not be permitted to conduct a half-hearted inquiry regarding the SOPs associated with the design and development of their TVT products before this Rule 30(b)(6) deposition and then conduct a thorough and vigorous inquiry before trial. "This would totally defeat the purpose of the discovery process." *Id.*

Defendants' argument that this topic is improper for a Rule 30(b)(6) deposition as the information can be more efficiently transmitted by a document production also lacks merit. Plaintiffs are entitled to the SOPs and, further, are entitled to obtain additional information regarding the SOPs from a corporate representative. By Defendants' own admission, the TVT

design and development projects were long-term and presumably rather complex. Plaintiffs should be permitted to ask a corporate representative about the history of the various SOPs associated with Defendants' TVT products, reasons for revisions, and should be able to confirm the contents of Defendants' SOPs at all relevant times.

B. Topic b: The complete design history file for the Devices, including each component part of the file, the custodian responsible for the file and the maintenance of the file.

Defendants lodged several objections to this subject matter. In an effort to reach a compromise, Plaintiffs agreed to be more specific and reformulated the topic to: (1) what makes up the Design History File ("DHF"); (2) what are the component parts of the DHF; (3) the custodian of the DHF; (4) how the DHF is maintained; and (5) the Bates ranges for each DHF.

Defendants object to item (5), arguing that it is an inappropriate subject for a 30(b)(6) deposition. Defendants acknowledge that each of the products at issue has a Design History File. However, Defendant argues that they are voluminous and "no company witness could possibly testify as to the completeness of a particular DHF presented to him or her." (Doc. No. 517 at 4.) Defendants further argue that the corporate designee was not involved in Bates stamping the documents and, therefore, cannot personally verify the accuracy of a produced copy. *Id.*

A design history file is "a compilation of records which describes the design history of a finished device." FDA 21 CFR § 820.30(e). Pursuant to FDA regulations, "[e]ach manufacturer shall establish and maintain a DHF for each type of device. The DHF shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part." FDA 21 CFR § 820.30(j). A "design history file" is made up of historical records that document the development of a medical device over time. This record is used to prove compliance with FDA regulations and, as such, is subject

to an audit by the FDA at any time. *Baxter Healthcare Corp. v. Fresenius Med. Care Holding, Inc.,* C 07-1359 PJH (JL), 2008 WL 5272186 (N.D. Cal. Dec. 15, 2008).

Defendants' argument that "no company witness could possibly testify as to the completeness of a particular DHF presented to him or her" is meritless. (Doc. No. 517 at 4.) As stated, pursuant to FDA regulations, Defendants were and are required to create and maintain a DHF for each of their products. Moreover, Defendants' DHFs are subject to an audit by the FDA at any time. Therefore, Defendants, at all times, must be able to identify and produce a DHF for each of its products. To argue that they are currently unable to do so for purposes of a deposition is nonsensical.

Similarly, Defendants' argument that its corporate designee cannot personally verify the accuracy of a produced copy because he was not involved in Bates stamping the documents is also meritless. With respect to a 30(b)(6) deposition, "[t]he duty of preparation goes beyond matters personally known to the designee or to matters in which the designee was personally involved, and if necessary the deponent must use documents, past employees or other resources to obtain responsive information." *Harris v. New Jersey,* 259 F.R.D. 89, 92-93 (D.N.J. 2007) (citing *United States v. Taylor,* 166 F.R.D. 356, 361 (M.D.N.C.1996)); *see also Starlight Int'l, Inc.* 186 F.R.D. at 638-39 (holding that while preparing for a 30(b)(6) deposition may be burdensome, this is "merely the result of the concomitant obligation from the privilege of being able to use the corporate . . . form in order to conduct business.").

Here, Plaintiffs simply seek to depose a corporate designee with knowledge regarding the Bates ranges for each DHF to ensure accuracy and completeness. As Defendants are required to maintain a DHF for all of their devices pursuant to FDA regulations, Defendants should be able to identify a complete DHF for each of their TVT products. Regardless of whether or not the

corporate designee was personally involved in Bates stamping the DHFs, he must use documents, past or present employees, or other resources to obtain the responsive information.

C. Topic c: Members and procedures of the Product Development Team for the Devices.

Defendants object to this subject matter, arguing that it is overbroad and unduly burdensome and provides insufficient notice under Rule 30(b)(6). In support of this argument, Defendants state that the design and development projects encompassed more than twelve years. Defendants further argue that the topic is vague and ambiguous, stating that "various witnesses may consider the same individual to be 'on' or 'not on' the design team for a particular device." (Doc. No. 517 at 5.) Lastly, Defendants argue that the information sought is more readily available to Plaintiffs from other sources, such as the design history files.

It is well-established that information or materials that are necessary to enable a party to prepare his case or facilitate proof at the trial or progress of the trial should be produced even though there will be an inconvenience or burden on the party producing them. *Hanover Shoe, Inc. v. United Shoe Machinery Corp.*, 207 F. Supp. 407, 409 (M.D.Pa.1962). *See also U.S. v. American Optical Co.*, 39 F.R.D. 580, 587 (N.D. Cal.1966) ("the fact that the production of documents may involve inconvenience and expense is not alone sufficient reason for refusing discovery which is otherwise appropriate."); *Rockaway Pix Theatre, Inc. v. Metro-Goldwyn-Mayer, Inc.*, 36 F.R.D. 15, 16 (E.D.N.Y. 1964) ("all sources of information should be made available regardless of expense . . . and the mere fact that production would be onerous or inconvenient is not, per se, grounds for denial of a Rule 34 motion."). Moreover, as stated, while courts have recognized that preparing for a Rule 30(b)(6) deposition can be burdensome, "this is merely the result of the concomitant obligation from the privilege of being able to use the

corporate [or other organizational] form in order to conduct business." *Starlight Int'l Inc.*, 186 F.R.D. 626, 638-39 (D. Kan. 1999); *see also Murphy v. K-Mart Corp.*, 255 F.R.D. 497, 507 (D.S.D. 2009) (recognizing that the burden on a corporation to prepare a knowledgeable Rule 30(b)(6) deponent "may be onerous," but stating that the court "is not aware of any less onerous means of assuring that the position of a corporation . . . can be fully and fairly explored.") Consequently, Defendants' argument that the topic c – "members and procedures of the Product Development Team for the Devices" – is unduly burdensome is without merit.

Defendants further argue that the topic is vague and ambiguous because one witness may consider an individual to be a member of the Product Development Team, while another witness may disagree. This argument clearly fails.

> The Rule 30(b)(6) designee does not give his personal opinions. Rather, he presents the corporation's "position" on the topic. [Citations omitted.] Moreover, the designee must not only testify about facts within the corporation's knowledge, but also its subjective beliefs and opinions. [Citation omitted.] The corporation must provide its interpretation of documents and events. [Citation omitted.] The designee, in essence, represents the corporation just as an individual represents him or herself at a deposition. Were it otherwise, a corporation would be able to deceitfully select at trial the most convenient answer presented by a number of finger-pointing witnesses at the depositions. [Citation omitted.]

United States v. Taylor, 166 F.R.D. 356, 361 *aff'd*, 166 F.R.D. 367 (M.D.N.C. 1996). As such, Plaintiffs, by way of their Rule 30(b)(6) deposition notice, do not seek the personal opinions of Defendants' corporate designee regarding Product Development Team members; rather, they seek the corporations' knowledge, beliefs and opinions regarding this issue.

Lastly, Defendants argue that the information sought is more readily available to Plaintiffs from other sources, such as the design history files. This argument is contradicted by Defendants' own argument immediately above, i.e., that opinions may differ with respect to who

was part of the Product Development Team. Moreover, presumably, there were members of the Product Development Team whose names do not appear in the design history files. For all of these reasons, Plaintiffs are entitled to the corporations' knowledge, beliefs and opinions regarding the members and procedures of the Product Development Team.

D. Topic i: All product names of the Devices.

Defendants object to this subject matter, arguing that the information sought is more readily available to Plaintiffs from other sources, such as the design history files. Notwithstanding, Defendants have agreed to provide Plaintiffs with a list of the project names it has identified for the Devices to date in advance of the corporate designee's deposition. While such a list certainly will be helpful, it is unclear from Defendants' response and objection to this topic whether they are agreeing that its corporate designee will have knowledge about and will be able to testify regarding this topic at the Rule 30(b)(6) deposition.

Assuming Defendants stand on the above-stated objection, it should be overruled. Upon information and belief, each of Defendants' five TVT products had various product names over the course of many years. Defendants seem to be suggesting that Plaintiffs should sift through the hundreds of thousands of pages of documents produced in this litigation in an attempt to find the various product names used and determine which names applied to which products. Contrary to Defendants' objection, the information sought by Plaintiffs is not "readily available" to Plaintiffs and, therefore, the Court should overrule Defendants' objection and order Defendants to produce a corporate designee with knowledge of and the ability to testify about the product names of Defendants' TVT products. While a list of product names will be helpful, Plaintiffs are entitled to obtain further information from Defendants' corporate designee regarding the product names.

E. Topic s: Any patents relating to the Devices and their predecessor mesh products.

Defendants lodged several objections to this subject matter. In an effort to reach a compromise, Plaintiffs agreed to be more specific and reformulated the topic to the devices identified in the 30(b)(6) deposition notices. Additionally, Plaintiffs agreed to limit the topic to: (1) the identity of the inventor; (2) the name of the patent holder; (3) a description of the patent; and (4) the patents for the devices from a design perspective.

Notwithstanding Plaintiffs' attempt to compromise, Defendants continue to object to this subject matter, as revised, arguing that it fails to describe with reasonable particularity the matters for examination. Defendants agree to produce a witness to testify about the United States patents directly related to the Devices. However, to the extent the subject matter includes patent filings in ex-United States jurisdictions (and it does, in fact, include such filings), Defendants object on the basis that it is not reasonably calculated to lead to the discovery of admissible evidence and is unreasonably burdensome. They further object on the basis that the information sought is equally available to Plaintiffs.

If the Court were to adopt Defendants' position, then few Rule 30(b)(6 depositions would ever take place. Defendants argue that this subject matter, even as revised, fails to describe with reasonable particularity the matters for examination. This argument is nonsensical. As stated, Plaintiffs have specified that the information sought is: (1) the identity of the inventor; (2) the name of the patent holder; (3) a description of the patent; and (4) the patents for the devices from a design perspective. Clearly, the subject matter is described with particularity.

Defendants seem to be objecting to this topic to the extent it seeks information regarding predecessor devices. This objection is meritless. It is undisputed at that various times, Defendants sought and obtained 510(k) clearance from the FDA to market their TVT devices.

The FDA's 510(k) clearance process sets forth a comprehensive scheme for determining whether a manufacturer has demonstrated that a product is substantially similar to a predicate device. *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 342 (2001). In this litigation, Plaintiffs allege, *inter alia*, that Defendants' TVT devices were not substantially similar to the predicate devices upon which Defendants sought clearance. Therefore, the predicate devices and the design thereof is highly relevant in this litigation, and consequently, "topic s" should not be limited to Defendants' TVT devices; rather, it should include the predecessor mesh products, as well.

As stated, to the extent this subject matter includes patent filings in ex-United States jurisdictions (and it does include such filings), Defendants object on the basis that it is not reasonably calculated to lead to the discovery of admissible evidence and is unreasonably burdensome. They further object on the basis that the information sought is equally available to Plaintiffs. As the Court may be aware, Defendants designed, developed, marketed and sold its TVT products in the United States and abroad, causing injuries to women around the world. There is no logical reason why this subject matter should be limited to United States patents. Clearly, information contained in a foreign patents regarding the design of Defendants' TVT product is highly relevant because this litigation involves, *inter alia*, claims that Defendants' TVT products were defectively designed and claims that the TVT products were not substantially similar to a predicate device, as required for FDA 510(k) clearance. Consequently, product design is a key issue in the case, and information contained in all patents relating to the devices is highly relevant.

Defendants' argument that this subject matter is unduly burdensome is also meritless. As stated, it is well-established that information or materials that are necessary to enable a party to

prepare his case or facilitate proof at the trial should be produced even though there will be an inconvenience or burden on the party producing them. *Hanover Shoe, Inc.*, 207 F. Supp. at 409; *see also Starlight Int'l Inc.*, 186 F.R.D. 626, 638-39 (D. Kan. 1999); *Murphy*, 255 F.R.D. at 507.

Finally, Defendants' argument that the information sought is readily available to Plaintiffs' also lacks merit. Defendants' internal documents, communications, drafts, processes, etc. regarding its patents, as well as documents and information pertaining to foreign patents, clearly are not readily available to Plaintiffs.

For all of these reasons, the Court should overrule Defendants' objections to topic s.

F. Topic kk: As they relate to design control and validation, the manufacturing processes, including but not limited to heating/extrusion/annealing/cooling/gamma radiation/sterilization.

Defendants lodged several objections to this subject matter. In an effort to reach a compromise, Plaintiffs have agreed to narrow the topic to the process by which Prolene mesh is manufactured, woven, tested, and sterilized, as well as similar information regarding the tools that accompany each device. Defendants have agreed to produce a witness or witnesses "who are knowledgeable about the manufacturing processes in general and will be prepared to discuss this topic at a high level." (Doc. No. 517 at 15.)

Because Defendants have lodged no clear objections to this topic, as revised, but instead, responded in a rather vague and ambiguous manner, Plaintiffs request that the Court order Defendants to produce a corporate designee with knowledge of and the ability to testify regarding topic kk, as revised, i.e., the process by which Prolene mesh is manufactured, woven, tested, and sterilized, as well as similar information regarding the tools that accompany each

device**.** A Court Order in this regard would clarify the topic in advance of the 30(b)(6) deposition and prevent disputes between the parties regarding the same.

G. Request No. 5(n): All company policies and procedures that apply to or relate to the design history file for the devices.

Defendants object to Request No. 5, generally, arguing that it is overbroad and unduly burdensome in that it is not limited in time. Defendants further argue that the documents are readily available to Plaintiffs from other sources. In response to Request No. 5(n), specifically, Defendants state that they will "continue to search to determine whether any documents responsive to this Request have been produced or should be produced." (Doc. No. 517 at 25.)

Request No. 5(n) is neither overbroad nor unduly burdensome. Throughout their Responses and Objections, Defendants repeatedly argue that various subject matters and requests are overbroad and unduly burdensome as the design and development of the TVT devices were projects that spanned over twelve years. (E.g., Doc. No. 517 at 2-3, 4.) As stated, the design of Defendants' TVT products is a key issue in this litigation, and Rule 30(b)(6) requires Defendants, by and through their corporate designee, to review all matters known or reasonably available to the corporation in preparation for the Rule 30(b)(6) deposition even if such preparation may be somewhat "burdensome." *Starlight Int'l Inc. v. Herlihy*, 186 F.R.D. 626, 638-39 (D. Kan. 1999). Therefore, Defendants' corporate designee must produce all company policies and procedures that apply or relate to the design history files for Defendants' TVT devices.

Defendants' argument that the documents are readily available to Plaintiffs from other sources is equally meritless. Defendants have failed to identify the "other sources." Moreover, Defendants state that they "continue to search to determine whether any documents responsive to

this Request have been produced or should be produced." (Doc. No. 517 at 25.) If Defendants struggle to determine what and where their own company policies and procedures are, such a task will surely be even more difficult for Plaintiffs. At this stage in the litigation, Defendants must locate and produce its company policies and procedures that apply to or relate to the design history file for the devices and cannot rely on a "will supplement" response.

For the reasons contained herein, Plaintiffs respectfully request the Court to overrule any and all objections to Topics a, b, c, i, s, and kk and Request No. 5(n) of Plaintiffs' Notices of 30(b)(6) Deposition and order Defendants to produce a corporate designee with knowledge of and the ability to testify regarding such topics. Further moving, Plaintiffs respectfully request an expedited hearing on this matter as the Rule 30(b)(6) deposition at issue is set for May 15, 2013.

Dated: May 9, 2013

Respectfully submitted,

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
This Document Applies To All Actions	:	Judge Joseph R. Goodwin

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2013, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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